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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,980	07/23/2001	Takayuki Suzuki	53375/1439	2298

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EXAMINER

MULCAHY, JOHN M

ART UNIT PAPER NUMBER

3739

DATE MAILED: 10/08/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/909,980

Applicant(s)

SUZUKI ET AL.

Examiner

John M. Mulcahy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-12 and 20 is/are pending in the application.
- 4a) Of the above claim(s) 7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 8-12 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10. 6) ☐ Other: _____

Election/Restrictions

1. Applicant's election without traverse of Group I and the species of Figs. 28-30 in Paper No. 8 is acknowledged. Claim 7 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 102

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1, 3, 4 and 8-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Matsui et al. (6,352,503) which shows an apparatus comprising:

As to claim 1: a first endoscope 1 adapted to be orally inserted into a body cavity; a holding device 186 extending out of a distal end of the first endoscope adapted to hold a point of a digestive wall of the body cavity where an artificial valve is to be formed (Figs. 44-47); a first needle 51 that is movable in a longitudinal direction of the first endoscope and that includes a sharp end adapted to penetrate the digestive wall, said first needle being adapted to be positioned at an oral side of the holding device before piercing the digestive wall (Fig. 11); a suture 52 adapted to pass through the digestive wall following the first needle; and a suture retaining 53 device having a grasping section adapted to grasp the suture after the suture has passed through the digestive wall (Fig. 11).

As to claim 3: the holding device 186 includes two jaws movable between an opened position and a closed position (described as "forceps," col. 17, line 29).

As to claim 4: the first needle has a hollow space disposed therein (for passage of the thread 52; see col. 9, lines 21-22).

As to claim 8: a guide member (either an external guide member, e.g., 36, or internal channel, e.g., 141) having a through hole provided side by side with the holding device; wherein the suture retaining device 53 is movable in the through hole of the guide member.

As to claim 9: the suture retaining device 53 includes two jaws movable between an opened position and a closed position (described as "forceps," col. 9, line 24).

As to claim 10: a second endoscope (Fig. 11), the first needle extends from a distal end of a second endoscope.

As to claim 11: the first needle is movable in a position nearer a handle section of the first endoscope than the distal end of the first endoscope is (needle treating tool 51 is retractable back through the channel of the endoscope; see col. 9, lines 20-21).

As to claim 12: the holding device 186 is adapted to holding a junction of a stomach and an esophagus (Figs. 44-47), and the first needle is adapted to be positioned in the oral side of the junction (Fig. 11).

Claim Rejections - 35 USC § 103

4. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Matsui et al. (6,352,503) as applied to claim 1 above, and further in view of Mangum (5,397,326).

Matsui et al. teaches the apparatus substantially as claimed, including the suture retaining device being adapted to pull the suture out from the body cavity (note that insertion tools 2 are retractable from tubes 36 and 37 of the endoscope), but fails to show a knot pushing device. However, Mangum shows an analogous endoscopic knot pushing device adapted to move a knot of the suture, which is formed outside the body cavity after the suture has pulled out from the body cavity by the suture retaining device, into the body cavity (col. 1, lines 52-64). It would have been obvious to the artisan to employ such a knot pusher with the Matsui et al. endoscope since Mangum teaches that such would allow the sutures to be tied with a convenient technique.

5. Claims 6 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsui et al. (6,352,503) as applied to claim 1 above, and further in view of Mills et al. (5,037,021).

Matsui et al. fails to show a second needle. However, Mills et al. shows an analogous endoscope (Fig. 8) having first 20 and second 30 needles positioned side by side and spaced apart by a certain distance (Fig. 6 embodiment). It would have been obvious to the artisan to modify Matsui et al. by using the sewing machine of Mills et al. since Mills et al. teaches that such would allow the sutures to be tied with a convenient technique.

Response to Arguments

6. Applicant distinguishes the surgical procedure taught in Figs. 44-47 of Matsui et al. However, such differences are irrelevant to the instant apparatus claims. In this respect it is noted that recitations that elements of the instant apparatus are "adapted to" a certain function are simply functional recitations and it is well established that a functional recitation, i.e., a recitation with respect to the manner in which an apparatus is intended to be employed, does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim. In re Pearson, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974); In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 136 USPQ 458 (CCPA 1963). Where, as here, the prior art reference is inherently capable of performing the function described in a functional limitation, such functional limitation does not define the claimed apparatus over such prior art reference, regardless of whether the prior art reference explicitly discusses such capacity for performing the recited function. In re Ludtke, 441 F.2d 660, 169 USPQ 563 (CCPA 1971). In addition, where there is reason to believe that such functional limitation may be an inherent characteristic of the prior art reference, Applicant is required to prove that the subject matter shown in the prior art reference does not possess the characteristic relied upon. In re Spada, 911 F.2d 705, 15 USPQ2d 1655 (Fed. Cir. 1990); In re King, 801 F.2d 1324, 1327, 231 USPQ 136, 138 (Fed. Cir. 1986); In re Ludtke, 441 F.2d at 664, 169 USPQ at 566 (CCPA 1971). Note that Matsui et al. teaches the use of a needle and

suture in Fig. 11. Inasmuch as the Matsui et al. apparatus is capable for use as outlined in the instant apparatus claims (see the above rejection), it is "adapted" as broadly claimed.

Final Rejection

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

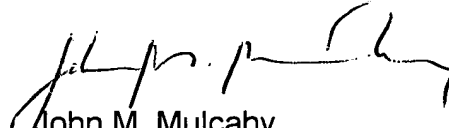
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John M. Mulcahy whose telephone number is (703) 308-3134. The examiner can normally be reached on M-F, 7:30-4:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. M. Dvorak can be reached on (703) 308-0994. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0873.



John M. Mulcahy
Primary Examiner
Art Unit 3739

John Mulcahy
October 6, 2003